

REMARKS

This responds to the Office Action dated October 18, 2006 (hereinafter "Office Action"), and the references cited therein.

No claims are amended, canceled, or added at the current time. Accordingly, claims 1-7, 9-13, 15-18, 20, 23-26, and 28-31 remain pending in this patent application. Applicant hereby respectfully requests further examination and reconsideration of the application in view of the following remarks.

§103 Rejection of the Claims

1. Claims 1-7, 9-13, 15-18, 20, and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobian et al. (U.S. Patent No. 5,796,044) (hereinafter "Cobian") in view of Helland et al. (U.S. Patent No. 5,545,201) (hereinafter "Helland"). Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claim 1:

Claim 1 recites a lead assembly comprising, among other things, a first conductor co-axial and non co-radial with an insulated second conductor and wherein "the first conductor and the second conductor are rotatable relative to one another." The Office Action expressly admits that Cobian does not disclose a lead assembly wherein the first conductor and the second conductor are rotatable relative to one another. (*See* Office Action at 3). Instead, the Office Action attempts to rely on Helland to establish this missing element. (*See* Office Action at 3). However, the lead assemblies of Cobian and Helland clearly teach against being combined with one another for the establishment of such relative conductor rotation. For example, Cobian states:

A biomedical lead conductor body formed of a coiled wire conductor that is sheathed loosely within a coiled insulative sheath of biocompatible and biostable material allowing a gap or space to be present between the exterior surface of the coiled wire conductor and the adjacent interior surface of the insulative sheath.

(Cobian at Abstract).

[The] objects of the present invention are realized in a medical lead body formed of a coiled wire conductor that is sheathed loosely within a separate coiled insulative sheath

allowing a gap or space to be present between the exterior surface of the coiled wire conductor and the adjacent interior surface of the insulative sheath.

(Cobian at col. 5, lns. 1-6).

In each of the above-described embodiments, it is assumed that all of the coiled wire conductors are insulated by a coiled insulative sheath that loosely receives it.

(Cobian at col. 11, lns. 62-64). In brief, Cobian requires an insulative sheath to be loosely positioned around a coiled wire conductor such that a gap or space is present between the exterior surface of the coiled wire conductor and the adjacent interior surface of the insulative sheath. On the contrary, Helland illustrates a lead assembly in which an insulative sheath is in direct contact with a first conductor on an outer surface thereof and is in direct contact with a second conductor on an inner surface thereof. (Helland at FIGS. 4, 5, and 6).

Applicant submits that the lack of a gap or space between the conductors and the insulative sheath in Helland would allow for the asserted rotation of the second conductor relative to the first conductor without resulting in kinking of the sheath. However, the same cannot be said for the modified lead assembly resulting from the combination of Cobian and Helland, as set forth in the Office Action. (See Office Action at 3). This is because the modified lead assembly set forth in the Office Action requires a gap or space to exist between the exterior surface of the first and second conductors and the adjacent interior surface of the loose-fitting insulative sheaths about equal in size to the diameter of the conductor itself. (See Cobian at col. 8, lns. 57-60). As a result of this gap or space, the relative rotation of the second conductor would likely result in kinking of the associated loose-fitting insulative sheath disposed therearound as portions thereof frictionally engage with adjoining portions of the lead assembly. In this way, the operability of the references taken in combination would be destroyed. According to the Federal Circuit, “[i]f references taken in combination would produce a ‘seemingly inoperative device,’ . . . such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness.” 262 F.3d 1339, 60 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 2001); *see also In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984)(holding that an inoperable modification teaches away). Therefore, the combination of Cobian and Helland is improper and fails to establish all elements of Applicant’s claim 1.

Because there is no *prima facie* case of obviousness of claim 1, Applicant respectfully requests withdrawal of this basis of rejection of claim 1. Claims 2-7, and 9-10 are dependent on claim 1 and are patentable for the reasons stated above, in addition to the elements recited in such claims.

Claims 4 and 5:

Additionally, regarding claims 4 and 5, Applicant cannot find (nor has the Office Action identified) in Cobian or Helland any disclosure of a lead assembly further comprising an insulative sleeve of polyurethane, polyimide, polysiloxane urethane, or a non-silicone material disposed between the first and the second conductor, as recited or incorporated in such claims.

As to claim 4, the Office Action asserts that the recitations therein may be found in Cobian at “fig. 9; col. 4 @ 11-15; col. 11 @ 4-6.” (Office Action at 3). Applicant submits that while figure 9 and col. 11, lns. 4-6 respectively illustrate and recite an insulative sleeve between an inner and an outer insulative sheath, and thus between a first and a second conductor, nowhere does Cobian disclose that this insulative sleeve “comprises a tube of polyurethane, polyimide, or polysiloxane urethane,” as recited in claim 4. Applicant further submits that, as recognized by the Office Action in its page 2 arguments, the text of Cobian at col. 4, lns. 11-15 pertains to the inner or the outer insulative sheath associated with the first or the second conductor, and not to the redundant insulative sleeve therebetween to which claim 4 pertains. (Office Action at 2; *see also* Cobian at col. 4, lns. 7-15).

As to claim 5, the Office Action asserts that the recitations therein may be found in Cobian at “col. 5 @ 57-67; col. 12 @ 42-50.” (Office Action at 3). Applicant submits that such cited portions of Cobian pertain to the inner and the outer insulative sheath of the first and the second conductors, and not the insulative sleeve therebetween to which claim 5 pertains. That is, the cited portions of Cobian fail to disclose an insulative sleeve “comprised of a non-silicone material,” as recited in claim 5.

According to the M.P.E.P. § 2142, the prior art reference(s) must teach or suggest all of the claim elements. Because not all elements of Applicant’s claims 4 and 5 can be found in Cobian or Helland, Applicant respectfully requests withdrawal of this basis of rejection of claims 4 and 5.

Claim 11:

Among other things, claim 11 recites a lead assembly comprising a first conductor co-axial and non co-radial with a relatively rotatable second conductor, at least one of which is insulated, and a “tubular insulative sleeve comprising one or both of polyurethane or polyimide” disposed between the two conductors. To this end, Applicant hereby incorporates by reference the relevant case law and arguments asserted above in association with claims 1 and 4 (i.e., Cobian teaches against being combined with the asserted relative conductor rotation of Helland due to operability destruction of the lead assembly therein; and the cited portions of Cobian do not disclose an insulative sleeve comprising polyurethane or polyimide).

Because all elements of Applicant’s claim 11 cannot be found in Cobian or Helland, and further there is no motivation to combine such references, Applicant respectfully requests withdrawal of this rejection of claim 11. Claims 12-13, 15-17, and 30-31 are dependent on claim 11 and are patentable for the reasons stated above, in addition to the elements in such claims.

Claim 30:

Additionally, regarding claim 30, Applicant cannot find (nor has the Office Action identified) in Cobian or Helland any disclosure of a lead assembly wherein a tubular insulative sleeve between a first and a second conductor is rotatable relative to the first conductor, as recited or incorporated in such claim. The Office Action asserts that this subject matter may be found in Cobian at “col. 4 @ 7-15; col. 5 @ 12-60; col. 11 @ 4-6.” (Office Action at 3). Applicant submits that while the text of col. 11, lns. 4-6 recites an insulative sleeve between an inner and an outer insulative sheath, and thus between a first and a second conductor, nowhere does Cobian disclose that this insulative sleeve “is rotatable relative to the first conductor,” as recited in claim 30. Applicant further submits that the other Office Action cited portions of Cobian (i.e., col. 4, lns. 7-15; col. 5, lns. 12-60) pertain to the inner or the outer insulative sheath associated with the first or the second conductor, and not to the redundant insulative sleeve therebetween to which claim 30 pertains. (Office Action at 3; *see also* Cobian at col. 4, lns. 7-15).

According to the M.P.E.P. § 2142, the prior art reference(s) must teach or suggest all of the claim elements. Because not all elements of Applicant’s claim 30 can be found in Cobian or Helland, Applicant respectfully requests withdrawal of this basis of rejection of claim 30.

Claim 18:

Among other things, claim 18 recites a method comprising “disposing one or both of polyurethane or polyimide tubing between [a] first conductor and [a] second conductor.” To this end, Applicant hereby incorporates by reference the relevant case law and arguments asserted above in association with claim 4 (i.e., the cited portions of Cobian do not disclose an insulative sleeve comprising polyurethane or polyimide).

Because all elements of Applicant’s claim 18 cannot be found in Cobian or Helland, Applicant respectfully requests withdrawal of this rejection of claim 18. Claims 20 and 23 are dependent on claim 18 and are patentable for the reasons stated above, in addition to the elements in such claims.

2. Claims 23-26, 28 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobian and Helland in view of Nelson et al. (U.S. Patent No. 6,249,708) (hereinafter “Nelson”). Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claim 24:

Claim 24 recites a method comprising, among other things, providing a second conductor having a coiled configuration having a second outer coil diameter and “heat shrinking PTFE or ETFE on the second outer coil diameter.” The Office Action expressly admits that Cobian as modified does not disclose the application of “heat shrunken Teflon™ material on the second outer coil diameter.” (Office Action at 4). Instead, the Office Action attempts to rely on Nelson for this missing element. (See Office Action at 4). However, the lead assembly of Cobian teaches against being combined with the lead assembly of Nelson “to reinforce the assembly” as asserted in the Office Action. (Office Action at 4). For example, Cobian states:

In each of the above-described embodiments, it is assumed that all of the coiled wire conductors are insulated by a coiled insulative sheath that loosely receives it.

(Cobian at col. 11, lns. 62-64).

Advantageously, the coiled wire insulative sheaths loosely receiving the coiled wire conductors decrease the probability that defects in the coiled wire insulative sheath will result in mechanical fracture or deterioration of the lead conductor.

(Cobian at col. 6, lns. 1-5). In brief, Cobian relies on a gap between the insulative sheaths and the associated coiled wire conductors to enhance the overall survivability of the lead. In contrast to Cobian, Nelson “teach[es] [a] lead construction using heat-shrunk Teflon™ (38) for the purpose of insulating the central core conductor (34).” (Office Action at 4). Because Nelson teaches away from the required gap of Cobian, the combination of Cobian and Nelson is improper and fails to establish all elements of Application’s claim 24. As stated by the Federal Circuit, a factor cutting against a finding of motivation to combine or modify the prior art is when the prior art teaches away from the claimed combination. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 U.S.P.Q. 416 (Fed. Cir. 1986).

Because there is no *prima facie* case of obviousness of claim 24, Applicant respectfully requests withdrawal of this basis of rejection of claim 24. Claims 25-26 and 28-29 are dependent on claim 24 and are patentable for the reasons stated above, in addition to the elements recited in such claims.

Claim 23:

Additionally, regarding claim 23, Applicant submits that without the use of his disclosure, one of ordinary skill in the art would not have been motivated to combine the teachings of Cobian and Nelson. To this end, Applicant hereby incorporates by reference the relevant case law and arguments asserted above in association with claim 24 (i.e., the combination of Cobian and Nelson is improper, as the latter teaches away from the required gap of the former, among other things).

Because there is no *prima facie* case of obviousness of claim 23, Applicant respectfully requests withdrawal of this basis of rejection of claim 23.

3. Claim 31 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobian and Helland in view of Altman et al. (U.S. Patent No. 5,845,396) (hereinafter “Altman”). Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claim 31 recites a lead assembly comprising, among other things, a first conductor having a first outer filar diameter and a second conductor having a second outer filar diameter, and wherein “a coating of polyimide surrounds the first outer filar diameter and the second outer filar diameter.” The Office Action expressly admits that Cobian as modified does not disclose a

lead assembly wherein the first outer filar and the second outer filar are coated with polyimide. (Office Action at 5). Instead, the Office Action attempts to relay on Altman to establish this missing element. (See Office Action at 5).

Applicant submits, however, that no legally sufficient motivation exists to combine the teachings of Cobian with the teachings of Altman to make the specific combination recited in claim 31. According to the Federal Circuit, “[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.” *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). The Office Action asserts it would have been obvious to have used the polyimide coating of Altman with the lead assembly of Cobian as it provides “an alternate material construction.” (Office Action at 5). Applicant submits that such assertion *prima facially* fails to satisfy the requirements of 35 U.S.C. § 103, as it fails to suggest a motivation to make the substitution. Rather, such assertion submittedly amounts to a mere trade-off. As stated by the Federal Circuit, “[t]rade-offs often concern what is feasible, not what is, on balance, desirable. Motivation to combine requires the latter.” *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 53 U.S.P.Q.2d 15080 (Fed. Cir.), *cert. denied*, 530 U.S. 1238 (2000).

Because there is no objective evidence of record for the Office Action’s assertion that it would have been obvious to combine the teachings of Cobian and Altman, Applicant respectfully requests withdrawal of this basis of rejection of claim 31.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited and encouraged to telephone Applicant's attorneys Greg W. Smock at (612) 373-6956 or Catherine I. Klima-Silberg at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 18 day of January 2007.

Name

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